

4. (3x Amended) The method of claim 31, wherein a physical, chemical, electrical, or sonic penetration enhancer is not used.

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5. (Amended) The method of claim 31, wherein the immune response is not an allergic reaction.

6. (Amended) The method of claim 31 further comprising applying alcohol to the intact skin prior to application of the formulation.

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10. (Amended) The method of claim 31, wherein the antigen has a molecular weight greater than 500 daltons.

11. (2x Amended) The method of claim 31, wherein the antigen is derived from a bacterium.

12. (2x Amended) The method of claim 31, wherein the antigen is derived from a virus.

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13. (2x Amended) The method of claim 31, wherein the antigen is derived from a fungus or parasite.

14. (Amended) The method of claim 31, wherein the antigen is selected from the group consisting of carbohydrate, glycolipid, glycoprotein, lipid, lipoprotein, phospholipid, and polypeptide.

15. (2x Amended) The method of claim 31, wherein the formulation comprises a live or an attenuated live virus and the antigen is expressed by the live or attenuated live virus.

16. (Amended) The method of claim 31, wherein the antigen is a polypeptide of greater than 500 daltons molecular weight.

17. (Amended) The method of claim 31, wherein the antigen is multivalent.

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20. (2x Amended) The method of claim 1, wherein said at least one adjuvant activates the Langerhans cell.

21. (2x Amended) The method of claim 1, wherein said at least one adjuvant enhances antigen presentation to a lymphocyte.

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27. (2x Amended) The method of claim 31, wherein the formulation is a cream or gel or emulsion or ointment.

28. (Amended) The method of claim 1, wherein the formulation further comprises a dressing.

29. (Amended) The method of claim 31, wherein the formulation is applied to intact skin covering more than one draining lymph node field.

30. (3x Amended) A method of immunization comprising hydrating intact skin of an organism and applying a formulation to the hydrated, intact skin, wherein the formulation consists essentially of one or more ADP-ribosylating exotoxins or derivatives thereof having adjuvant activity, and an effective amount of said one or more ADP-ribosylating exotoxins or derivatives thereof is not encapsulated.

31. (3x Amended) A method of inducing an immune response comprising:

(a) hydrating intact skin of an organism and applying a formulation to the hydrated, intact skin, wherein the formulation comprises (i) at least one antigen which is derived from a pathogen and (ii) at least one adjuvant comprising an ADP-ribosylating exotoxin or derivative thereof, and at least some antigen which is not encapsulated induces the immune response; and

(b) inducing the immune response in the organism without perforating the skin, wherein the immune response is specific for the antigen.

32. (4x Amended) A method of inducing an immune response comprising:

(a) hydrating intact skin of an organism and applying a formulation to the hydrated, intact skin, wherein the formulation comprises (i) at least one antigen which is derived from a pathogen and (ii) at least one adjuvant comprising an ADP-ribosylating exotoxin or derivative thereof, and at least some antigen which is not encapsulated induces the immune response;

(b) activating an antigen presenting cell with the at least one adjuvant; and

(c) presenting the at least one antigen or epitope thereof on a cell surface of the antigen presenting cell to a lymphocyte, thereby inducing the immune response in the organism.

33. (3x Amended) A method of inducing an immune response comprising:

(a) applying epicutaneously to hydrated, intact skin of an organism an effective amount of at least one antigen derived from a pathogen and which is not encapsulated,

(b) activating a Langerhans cell underlying the organism's skin with at least one adjuvant comprising an ADP-ribosylating exotoxin or derivative thereof,

(c) signaling the Langerhans cell to migrate to a lymph node of the organism and mature into a dendritic cell therein, and

(d) presenting the at least one antigen or epitope thereof on a cell surface of the dendritic cell to a lymphocyte; thereby inducing the immune response in the organism, wherein the immune response is specific for the at least one antigen.

61. (Amended) The method of claim 31, wherein the formulation comprises a whole organism, and the antigen is expressed by the whole organism.

62. (2x Amended) A method of immunization comprising hydrating intact skin of an organism and applying a formulation without lipid vesicles to the hydrated, intact skin,

87 wherein the formulation is comprised of an effective amount of one or more at least partially purified ADP-ribosylating exotoxins or derivatives thereof having adjuvant activity.

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88 81. (Amended) The method of claim 1, wherein at least one adjuvant is bacterial DNA.

89 82. (Amended) The method of claim 1, wherein at least one adjuvant is an ADP-ribosylating exotoxin or a derivative thereof which binds a receptor on antigen presenting cells.

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90. (Amended) The method of claim 31, wherein the formulation further comprises a dressing.

91. (Amended) The method of claim 31, wherein at least one adjuvant is further comprised of a cytokine or a chemokine.

92. (Amended) The method of claim 31, wherein at least one adjuvant is further comprised of bacterial DNA.

93. (Amended) The method of claim 31, wherein at least one adjuvant is an ADP-ribosylating exotoxin or a derivative thereof which binds a receptor on antigen presenting cells.

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103. (Amended) The method of claim 1 further comprising applying the formulation with an occlusive dressing.

94 104. (Amended) The method of claim 30 further comprising applying the formulation with an occlusive dressing.

105. (Amended) The method of claim 31 further comprising applying the formulation with an occlusive dressing.

106. (Amended) The method of claim 32 further comprising applying the formulation with an occlusive dressing.

107. (Amended) The method of claim 62 further comprising applying the formulation with an occlusive dressing.

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Kindly add the following new claims.

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108. (New) The method of claim 1, wherein the formulation consists essentially of one or more ADP-ribosylating exotoxins or derivatives thereof having both antigen and adjuvant activities.

109. (New) The method of claim 31, wherein the formulation consists essentially of one or more ADP-ribosylating exotoxins or derivatives thereof having both antigen and adjuvant activities.

110. (New) The method of claim 32, wherein the formulation consists essentially of one or more ADP-ribosylating exotoxins or derivatives thereof having both antigen and adjuvant activities.

111. (New) The method of claim 33, wherein the formulation consists essentially of one or more ADP-ribosylating exotoxins or derivatives thereof having both antigen and adjuvant activities.

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#### **IN THE DRAWINGS**

Kindly enter the attached formal drawings.